



# Emory Single IRB (sIRB) Process – What Researchers Need to Know

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# Agenda

- ▶ What is a single IRB (sIRB)?
- ▶ Why is reliance required?
- ▶ What is process when Emory is the sIRB?
- ▶ What happens after approval?

# What is an sIRB?

- ▶ A single IRB (sIRB) is the IRB that provides oversight for all participating sites within the U.S. that are engaged in non-exempt human subjects research.
- ▶ At Emory, we use this term when the Emory IRB is the reviewing IRB for other sites that will enroll participants and have their own consent forms.

# Why do we have Reliance?

- ▶ Goals of using a single IRB for multi-site research:
  - ❖ Streamline the ethical review of research
  - ❖ Consistency amongst sites (materials, determinations)
  - ❖ The sIRB reviews ALL reportable events occurring in the study



# Regulatory Requirements for sIRB

## NIH Single IRB Mandate

- January 25, 2018
- NIH-funded Multi-site studies conducting same protocol
- Only U.S. sites
- Applies to non-NIH funded studies if the NIH is a site

## Cooperative Research Component of Revised Common Rule

- January 20, 2020
- Federally-funded cooperative research studies involving more than one institution
- Only U.S. sites
- Does **not** apply to studies that have been approved by any IRB prior to January 20, 2020 or where funding agency determined sIRB not appropriate

# FDA Requirement is Coming!

In September 2022, the FDA announced their proposal to require use of a single IRB for FDA-regulated cooperative research conducted in the U.S. This will expand the single IRB requirement to pharma studies that are currently not subject to the other two requirements.

When will  
Emory IRB will  
serve as the  
sIRB?

Multi-site studies where use of an sIRB  
is required

Emory PI is lead PI/prime awardee

U.S. sites only

5 or less sites



## Step 1: Consult with Reliance Team

- ▶ If applying for a federal grant and want Emory to serve as the sIRB, contact the reliance team early. Send email to [irb.reliance@emory.edu](mailto:irb.reliance@emory.edu) to request to meet with the reliance team to review the specifics of the study and sites.
- ▶ Provide complete information about the procedures that will be conducted at each of the participating sites (pSites).
- ▶ Whether Emory or another IRB is serving as the sIRB, be sure to include sIRB review fees in the grant budget.



# What is impact to Emory study team?

- ▶ Study Coordinator or Project Manager is needed to do the following:
  - ❖ Communicate with study teams and IRBs at relying institutions regarding study start up
  - ❖ Set up the study in IREx (an electronic platform for collecting and disseminating documents to pSites including approval letters and stamped consent forms) **OR** be responsible for collecting and disseminating documents to pSites via email.
  - ❖ Collect information from pSites at Continuing Review and submit the CR for Emory and the pSites to the Emory IRB as well as disseminate CR approval letters and stamped consent forms to pSites
  - ❖ Submit modifications and any RNIs to the Emory IRB on behalf of pSites and disseminate IRB approvals to them

## Step 2: Submit to the Emory IRB

- ▶ Emory study team will submit study-wide materials to the Emory IRB for approval (as applicable to the study)
  - ▶ Protocol
  - ▶ Master consent form(s)
  - ▶ Investigator Brochure
  - ▶ Surveys/questionnaires
  - ▶ Recruitment materials

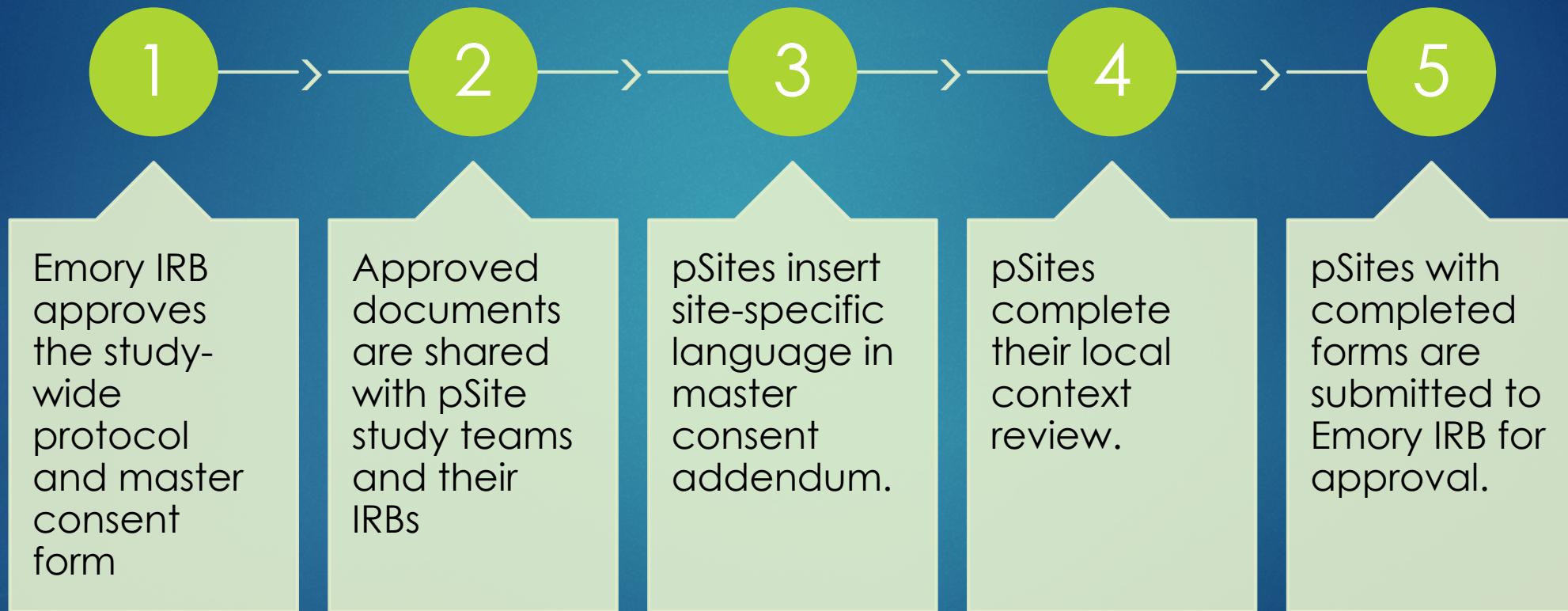
# Step 3: Addition of pSites

Once approved, the Emory study team provides instructions to pSites who will need to submit to their local IRBs to request reliance. Each pSite will need to begin the process as soon as they are provided the Emory IRB approval documents.

It is the responsibility of the Emory study team to follow up with pSites for completion of the required documents including site-specific consent form addendum, reliance document, and local context form.

Once all of the required documents are completed for each pSite, the pSite submission is reviewed by the Emory IRB.

# Reliance Process



# What does the IRB need to consider when approving a pSite?

- ▶ Do all study team members have current CITI training?
- ▶ Do any have COIs? If yes, is there a management plan?
- ▶ Does consent include site's required language (e.g. cost, in case of injury, HIPAA authorization as applicable)?
- ▶ Does relying institution have any concerns about study?
- ▶ Is there info from ancillary reviews to consider?
- ▶ Are there local laws or institutional policies applicable to the research?

# Post-Approval



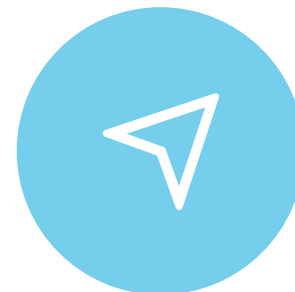
Once the site's documents have been reviewed, the pSite can be approved.



Each pSite receives an IRB approval letter and stamped consent form.



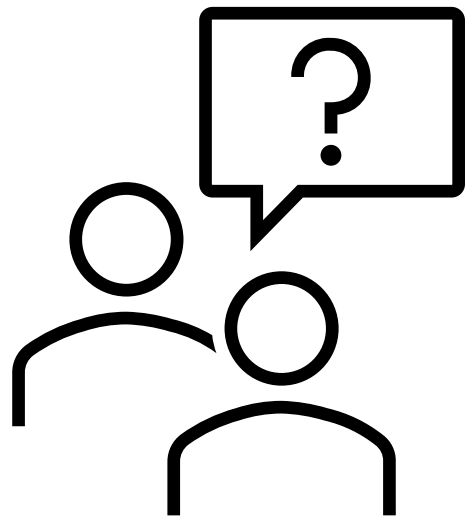
The Emory study team is responsible for submitting CRs, modifications and RNIs to the Emory IRB on behalf of all study teams



Study staff changes will be tracked by the local IRBs.

# Take Aways

- ▶ Contact Reliance Team at [irb.reliance@emory.edu](mailto:irb.reliance@emory.edu) if you are planning to submit a federal grant and want Emory to be the sIRB
- ▶ The Emory IRB has a choice about being the sIRB – We will review on case-by-case basis. Remember: No more than 5 pSites and Emory as prime awardee
- ▶ Single IRB fees (if reviewing IRB charges) must be included in grant budgets
- ▶ Emory PI will need a project manager/strong coordinator if using the Emory IRB



# Question?

[lrb.reliance@emory.edu](mailto:lrb.reliance@emory.edu)